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Patent
Case No.: 48317US028

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	JAPUNTICH, DANIEL A.		
Application No.:	09/680465	Group Art Unit:	3761
Filed:	October 6, 2000	Examiner:	Aaron J. Lewis
Title:	FIBROUS FILTRATION FACE MASK HAVING A NEW UNIDIRECTIONAL FLUID VALVE		

BRIEF ON APPEAL

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November 6, 2003
Date

Signed by: Susan M. Dacko

Dear Sir:

This is an appeal from the Office Action mailed on May 7, 2003. This Brief is being filed in triplicate. The fee required under 37 CFR § 1.17(c) for the appeal should be charged to Deposit Account No. 13-3723.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellants bring to the Board's attention the following related cases: 08/240,877, 09/678,579, 09/678,580, 09/680,465 and 09/837,714.

STATUS OF CLAIMS

Claims 33, 35-57, 60-63, and 66-83 are pending in this application and are the subject of this appeal.

STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF THE INVENTION

Persons who work in contaminated environments commonly wear filtering face masks over their nose and mouth to protect themselves from inhaling airborne pollutants. Many known filtering face masks have employed a cup-shaped mask body that includes a filter layer and that is adapted to fit over a wearer's nose and mouth. Exhalation valves have been used on these masks to rapidly purge exhaled air from the mask interior. The rapid removal of exhaled air makes the mask more comfortable to wear.

Because exhalation valves are powered by the wearer's lungs, valves that open easier during each exhalation improve wearer comfort because less work is needed to operate the valve. Valves that open easier may also be beneficial in that they can more rapidly purge warm, moist, exhaled air from the mask interior. In the working examples of the present invention, applicants have demonstrated an ability to remove so much air (>100%) from the mask interior, during a simulated exhalation, that an influx of cool ambient air occurred (see Table 2, particularly Examples 11-13). For filtering face masks that have porous mask bodies, this is quite an achievement because it demonstrates, for the first time, that a filtering face mask can operate as a cool-air aspirator — drawing cool, low humidity, air into the mask interior through the filter media to substantially improve wearer comfort. No prior art exhalation valve on a filtering face mask had yet demonstrated such a feat during an exhalation, particularly on a valve that is capable of having its flap remained closed under any orientation of the mask.

The most common type of exhalation valve that has been used on filtering face masks is a "button-style" valve. These valves typically have a circular flexible flap that is mounted to a valve seat through a central stake or button. The whole circumference of the flap is generally free to be lifted from the seal surface during an exhalation. An example of a button-style valve is shown in Figure 3 (cross-sectional side view) of UK patent application GB 2,072,516A to Simpson:

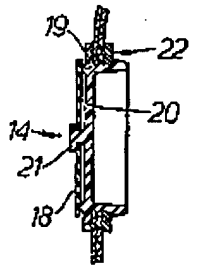


FIG. 3.

[Simpson Button-Style Valve]

Another example of a button-style valve is shown in U.S. Patent 4,873,972 to Magidson et al., assigned to Moldex/Metric Products Inc. and issued on October 17, 1989.

In addition to button-style valves, other valve structures have been used to purge exhaled air from the mask interior. For example, U.S. Patent 4,934,362 to Braun describes a valve, which when viewed from the side, has a parabolic valve seat. Like the button-style valves, the Braun valve has its flap mounted centrally to the valve seat:

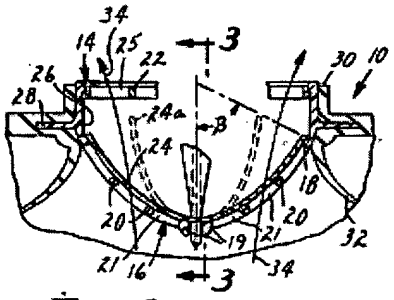


FIG. 2 22 14 25

This central mounting, however, can interfere with the flow of exhaled air through the valve and can cause exhaled air to be diverted into multiple flow streams, which discounts the moment arm that is needed to lift the flap from the seal surface. For these reasons, centrally-mounted valves may not perform as well as the valve invented by the appellants.[1]

As an alternative to a centrally-mounted valves, a "flapper-style" or "cantilevered" valve also has been disclosed as being suitable for use on filtering face masks. Figure 2 of the Simpson patent shows such a valve:

[1] Examples 4-6 in applicants' specification show the performance of the Braun valve compared to applicants' invention.

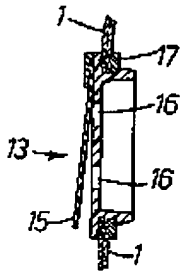


FIG. 2.

[Simpson Flapper Valve]

This flapper-style valve includes a "flexible circular flap member 15 of, for example, plastics material, which is arranged to cover and close valve opening 16 during an inhalation and to flex away from those openings during exhalation." To enable the flap member to flex, "a part of its peripheral portion, a segment of the flap member, is fixed in position, the remaining part of the flap member being left free." See Simpson at page 2, lines 37-46.

Although Simpson's flapper-style valve can provide a greater moment arm (than a centrally-mounted flap) for lifting the flap 15 from the seal surface to encourage quick displacement of exhaled air from the mask interior, the valve does suffer from a number of deficiencies, amongst them, the inability to keep the flap closed under any orientation of the valve. To keep its valve closed under neutral conditions — that is, when a wearer is neither inhaling nor exhaling — Simpson mounts the valve 12 on the top portion 1 of its duck-billed mask:

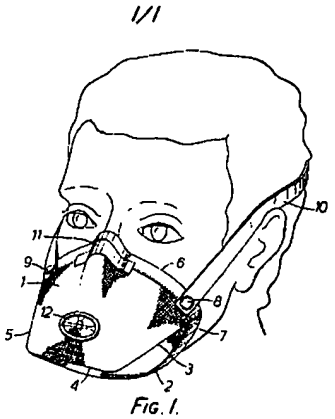


FIG. 1.

[Simpson Mask]

Simpson does not describe how to construct a flapper-style valve where the flap is pressed against a seal surface when a wearer is neither inhaling or exhaling. Simpson's valve therefore

relies on gravity for this purpose. This reliance on gravity, however, places limits on the locations where Simpson's valve can be placed on a cup-shaped mask without risking contaminant influx. And when the valve is not disposed directly in (or normal to) the path of the exhaled flow stream, the flap cannot take full advantage of the momentum of the exhale flow stream during an exhalation to encourage more rapid and complete opening of the valve. Without this ability, the displacement of exhaled air cannot be maximized, and aspiration effects are less likely to occur. In addition, because the Simpson valve does not have a pre-load on it, there is a great risk that the valve could remain open under certain conditions. Saliva and moisture commonly build up on an exhalation valve during use. The presence of these substances on the flap can cause the flap to stick to another surface such as a valve cover, when the flap opens in response to a force from an exhalation, or in Simpson's case from mere gravity. If the valve stays open, then contaminants can be directly drawn into the wearer's respiratory system during the next inhalation. Simpson recognizes that its valve may leak and accordingly suggests the use of an "antechamber" to prevent inhalation of "harmful atmosphere". See Simpson at p. 1 lines 58-64. The solution that Simpson proposes is entirely different from the solution proposed and claimed by the applicants of the subject invention.

Applicants' invention pertains to a filtering face mask 10 that comprises a mask body 12 that is adapted to fit over the nose and mouth of a wearer. The filtering face mask 10 also has an exhalation valve 14 that is attached to the mask body 10. This valve can be attached to the mask body directly in the path of the exhale flow stream. The exhalation valve comprises a valve seat 26 and a single flexible flap 24.

In applicants' invention, the flap 24 is supported on a valve seat 26 to provide a mask that exhibits better in performance over known exhalation valves:

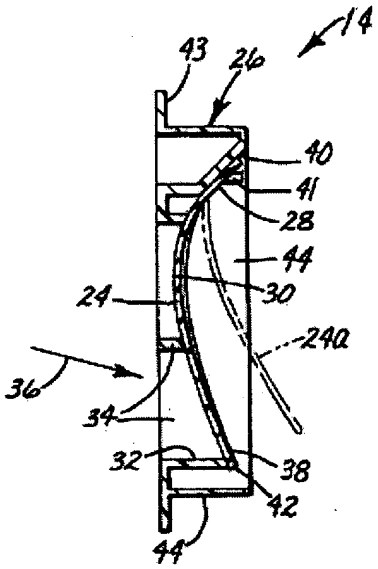


Fig. 3

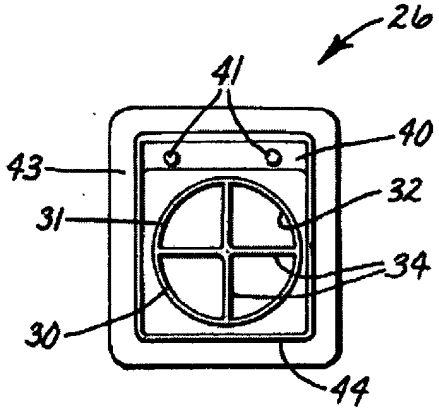


Fig. 4

In applicants' flapper valve, the flexible flap 24 would normally assume a flat configuration when no forces are applied to it, but the flap has a curved profile when viewed from the side in its secured position on the valve seat and is pressed towards the seal surface 31 in an abutting relationship with it when a fluid is not passing through the orifice.

Applicants' invention exerts a bias on the flap to prevent the unwanted influx of contaminants. Despite the bias, the flap's one free portion 38, however, can be readily lifted from the seal surface during an exhalation (as a bent cantilever) to allow large quantities of air to be rapidly purged from the mask interior (see applicants' specification at page 6, line 25 to page 9, line 29; see also Examples 4-13).

Although the resultant different structure and benefits of applicants' invention have not been taught in the prior art, they have, however, been utilized by investigators in this field after publication of applicants' invention. For example, the Louis M. Gerson Company introduced a mask in approximately March of 2001 (see attached McGinley Affidavit at paragraph 4.h.; copy attached as file Exhibit A — a sample of the Gerson mask is attached to this Appeal Brief as Exhibit B). The Gerson mask uses a flapper-style valve where a curved flap is positioned relative to the orifice to be pressed towards the seal surface under any orientation of the mask. Before publication of applicants' invention, Gerson sold masks that used button-style valves. In

addition, Magidson — an inventor of the subject matter used in the '972 Moldex patent mentioned above — described the use of a button-style valve on a filtering face mask in a 1988 patent application. But after the publication of applicants' invention, Magidson (in U.S. Patent 6,047,698 to Magidson et al. also assigned to Moldex-Metric Inc. and filed on August 20, 1998) described a flapper-style valve that supports the flexible flap non-centrally and operatively such that the flap is curved and is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve:

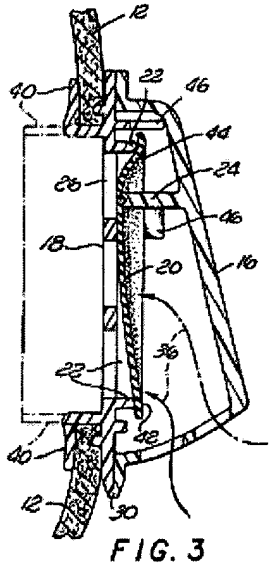


FIG. 3

[Magidson Valve]

Thus, while investigators in the pertinent field did not appreciate applicants' invention before it was published, these same investigators did choose to adopt it once it became publicly known.

ISSUES ON APPEAL

Issue 1 - Double Patenting

The obviousness-type double patenting rejection has been made provisionally since the application from which the rejection stems has not yet issued. When and if U.S. Patent Application 08/240,877 issues, applicants will consider filing a Terminal Disclaimer to overcome this rejection.

Issue 2 - Obviousness

Applicants' independent claims 33, 66, 67, and 81 have been rejected based on a combination of GB 2,072,516A to Simpson and U.S. Patent 3,191,618 to McKim. Simpson

describes a flapper-style exhalation valve for a filtering face mask that operates under temperatures and pressures generated by a human's respiratory system and at a person's breathing pace (typically 20 to 60 cycles per minute), and McKim describes a curved seat reed valve for a 2-cycle engine that would operate at internal combustion temperatures and pressures and at speeds on the order of 10,000 or 12,000 revolutions per minute (rpms). McKim's reed valve is made of rigid spring sheet material such as shim stock, which will not bend or flex under the force of gravity or in response to a wearer's exhalation. Would Simpson and McKim have rendered the subject matter of claims 33, 67, 68, and 81 obvious to a person of ordinary skill under the terms of 35 USC § 103(a)?

Issue 3 - Obviousness

A U.S. Patent 812,706 to Warbasse is cited as another secondary reference along with McKim and a U.S. Patent 4,934,362 to Braun. Warbasse describes a hood element 11 for use on a device that is placed over a person's nose and that is connect to a supply tube 16. Braun shows a flat grill 25 that covers an exhalation valve on a filtering face mask. Would the combination of Simpson, McKim, Warbasse, and Braun have rendered obvious the subject matter of claims 60-63 and 83, which claims recite a valve cover that has a fluid impermeable ceiling that increases in height?

Issue 4 - Obviousness

Claim 64 has been rejected based on a U.S. Patent 1,701,277 to Shindel. Claim 64, however, has been canceled, and therefore this rejection is not an issue in this case.

GROUPING OF CLAIMS

The independent claims and dependent claims that have been separately argued will stand or fall individually. No admission, however, is being made on the obviousness of the subject matter of the non-argued dependent claims with respect to the subject matter of the independent claims or argued dependent claims, from which they may depend.

ARGUMENTS OF APPELLANTS

Issue 2 - Obviousness of Claims 33, 66, 67, and 81 Based on Simpson and McKim

Simpson describes a flap valve 13 in its Figure 2 that comprises a flexible circular flap member 15:

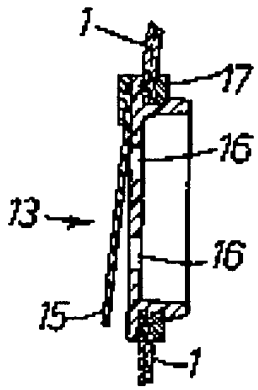
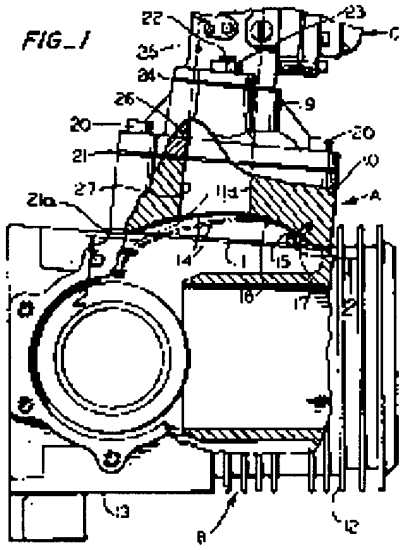


FIG. 2.

[Simpson]

The flap member 15 is made of a plastic material and is arranged to cover a closed valve opening 13 during an inhalation and to flex away from those openings during an exhalation (p. 2, lines 37-42). To allow flexing of the flap member 15, a part of its peripheral portion — that is, a segment of the flap member — is fixed in position and the remaining part of the flap member is left free (p. 2, lines 42-46). The valve is fitted in an aperture on the mask and is held in place by a retaining ring 17 (p. 2, lines 46-50). As shown in Simpson's Figure 1 reproduced above, the valve 12 is disposed on the top portion 1 of Simpson's duck-bill or pouch-shaped mask.

McKim discloses a curved seat reed valve for a 2-cycle engine:



[McKim]

The reed valve includes a valve reed 14 of spring sheet materials such as shim stock (col. 1, lines 60-61). The spring sheet material is secured by an anchor bar 15 and screws 17 to a curved seat 18 that is formed on the inner-engine side of the valve bock 10 (col. 1, lines 61-63). Curvature of the seat 18 corresponds to the normally flexed condition of the valve reed 14 when it is flexed laterally from its normally straight position as shown in Figure 3 (col. 1, lines 64-66). The normally flexed curvature of the reed is provided to eliminate float, or flutter from bounce when closing (column 1, lines 19-24; column 2, lines 55-62). The McKim valve is fashioned for use on high-speed engines, for example one that will turn at a speed on the order of 10,000 to 12,000 revolutions per minute (col. 2, lines 55-62). For a more modest speed, for example, 5,000 or 6,000 rpms, the curvature of the valve seat may be reduced to provide a freer, fuller opening of the valve at the lower speeds (column 2, lines 62-65).

The combination of Simpson and McKim would not have rendered applicants' invention obvious to a person of ordinary skill for the following reasons.

1. McKim is Not Analogous Art

The secondary reference, U.S. Patent 3,191,618 to McKim, cannot be applied as a reference against applicants' invention because the McKim patent does not reside in an analogous art.

As the Board is aware, a reference is not analogous and thus not relevant for determining obviousness unless it is either (1) within the field of the inventor's endeavor, or (2) is reasonably

pertinent to the particular problem that confronted the inventor.[2] Applicants' invention resides in the field of filtering face masks that use exhalation valves. McKim does not reside within this field of endeavor: it resides in the field of gasoline engines that use reed intake valves. McKim therefore does not satisfy part (1) of the two-part test. Thus, we only need to evaluate whether McKim meets part (2) of the test.

In the leading case that deals with "analogousness" under part (2) of the test, the Federal Circuit has explained that the USPTO needs to consider the purposes of both the cited disclosure and the invention when deciding whether a reference is reasonably pertinent to the particular problem that confronted the inventor:

> A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it** (emphasis added).[3]

In developing their invention, applicants sought to produce an exhalation valve that minimized exhalation pressure needed to open the valve and that allowed a greater percentage of exhaled air to be purged from the mask through the exhalation valve to improve wearer comfort while also allowing the valve to remain closed under any orientation (see applicants' specification at page 3, line 25 to page 5, line 34 and Examples 4-6 and 8-13). The McKim reference, however, deals with solving the problem of float or bounce, which may occur when a 2-cycle engine is operating at high rpms (see McKim at column 1, lines 20-24 and column 2, lines 55-62). McKim's concern for controlling float or bounce is not reasonably pertinent to the problems that applicants were involved with — namely, providing comfort to the mask wearer by allowing the valve to open under minimal pressure so that a greater percentage of exhaled air can be purged from the mask interior while also enabling the valve to remain closed under any orientation. As stated in the Bowers

[2] *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).
[3] *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

Declaration (attached as Exhibit C), investigators who work in the field of exhalation valves for filtering face masks are not concerned with problems of float or bounce:

> In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

Bowers' Declaration, paragraphs 11-13. Another person skilled in the field of exhalation valves for filtering face masks, Frank Fabin, who has worked on one design team and led another design team in the development of a new exhalation valve, stated the following with respect to McKim:

> My review of the McKim patent reveals a curved seat reed valve that is suitable for use in high rpm two-cycle engines. The reed valve comprises a thin, normally flat, single thickness, springy, sheet material, which, when relieved of external stresses will lie flat, but which is flexed lengthwise to define a curve. The reed valve is disclosed to be made of a spring sheet material, such as, for example, shim stock. The reed valve is disclosed to bear throughout its length against a valve seat, with the seating bias at the free end of the reed being as great as, or greater than, that throughout the remainder of the reed. The reed valve is indicated to be designed to seat quickly, effectively, and without float or bounce after each opening. The patent indicates that the reed valve is adaptable for use within an extremely high-speed engine, for example, one that will turn at a speed on the order of 10,000 or 12,000 revolutions per minute or at more modest speeds of 5,000 to 6,000 rpms.

> In my approximately 24 years of working in occupational health, I have not — nor am I aware of another person who works in this field who has — consulted a reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks.
>
> Filtering face masks posses the problem of creating a warm, moist, high CO_2 content environment around the nose and mouth of a person who wears a filtering face mask. Investigators in this field have pursued a goal of purging from the mask interior the largest amount of fluid possible while using the least amount of energy. Investigators therefore have pursued the particular goal of designing exhalation valves that open easily in response to the exhalation pressure developed in the mask interior during an exhalation. Exhalation valves that open under minimal pressure allow the warm, moist high CO_2 content air, to be more easily removed from the mask interior and thus require the wearer to expend less energy to operate the valve over an extended period of time. Exhalation valves typically operate under ambient environmental conditions in response to exhalation pressures generated by the wearer. These conditions are remarkably different from the environment (for example, temperatures and pressures) under which a reed valve operates in a two-cycle gasoline engine. The flexible flaps that are used in exhalation valves do not deal with problems of float, or flutter from bounce in closing like the reed valves described by McKim. The opening and closing of an exhalation valve occurs in cadence with a wearer's breathing pace, which is orders of magnitude less than the high rpms under which gasoline engines operate at. For these reasons and others, persons of ordinary skill in the filtering face mask and exhalation valve art, as far as I am aware, do not examine documents that pertain to reed valves for two-cycle gasoline engines in designing filtering face masks and the exhalation valves that are used on them. Documents that describe reed valves for two-cycle gasoline engines are not in the field of endeavor of persons who design exhalation valves for filtering face masks.

Fabin Affidavit (Exhibit D), paragraphs 8-10 (December 10, 2001).

The Bowers and Fabin declarations discussed above explain how McKim is concerned with a problem that is of no concern to the purpose of the present invention. Because the purpose of applicants' invention is not pertinent to the problem that McKim dealt with, namely float or bounce, the second prong of the test for qualifying as an analogous reference also has not been met. A person possessing ordinary skill in the art of filtering face masks that use exhalation valves therefore would not reasonably have been expected to solve the problem of lowering the airflow resistance force needed to open an exhalation valve through considering a reference that deals with eliminating float or bounce in a valve reed in a 2-cycle gasoline engine.

The Federal Circuit has clearly stated that when the reference "is directed to a different purpose, the inventor would accordingly have less motivation or occasion to consider it" and

therefore it would not be analogous.[4] **Accordingly, since the Examiner cannot establish that eliminating float or bounce is a purpose of applicants' invention, McKim cannot qualify as an analogous reference, and therefore the rejection based on McKim is accordingly in error.** This error is apparent when the leading case of the Federal Circuit is carefully examined.

In *In re Clay*, the Federal Circuit found the cited reference to be not analogous when (1) the prior art taught the use of a gel within a natural, underground, oil-bearing formation (to channel oil flow in a desired direction) and (2) the applicant, Clay, had invented the use of a gel to fill the confined dead volume of a man-made storage tank. Although both Clay and the prior art (Sydansk) both described technology that related to the use of gels in the petroleum industry, *the Sydansk reference was found to be nonanalogous because the purpose of the Sydansk teachings were different from the purpose of the Clay invention.* Sydansk was faced with the problem of recovering oil from rock, which was not pertinent to the problem with which Clay was involved, namely, preventing loss of stored product in a tank's dead volume. The court also found that the subterranean formation of Sydansk was not structurally similar to and did not operate under the same temperature and pressure and did not function like Clay's storage tanks.

As in *In re Clay*, the McKim reference also does not have the same purpose as the applicants' invention, it does not operate under the same temperature and pressure, and it does not function like the claimed invention. Float or bounce is a problem that occurs when a two-cycle engine operates at high rpms (10,000 to 12,000 rpms). It is not a problem that occurs in an

[4] *Id.; see also, SRI Int'l, Inc. v. Advanced Tech. Lab.*, 45 F.3d 443, 445 (Fed. Cir. 1995) ("The problem Green solved was how to compensate for changes in the spectral distribution of the return ultrasonic signal, with time or depth of penetration into a living organ, for enhanced image resolution and/or signal to noise ratio. The Minton reference, which relates to seismic prospecting circa 1946, almost thirty years prior to Green's filing date, would not have logically commended itself to Green's attention in considering how to compensate for changes in the spectral distribution of a received ultrasonic signal in an object such as a body part."); *In re Green*, 22 F.3d 1104, 1105 (Fed. Cir. 1994) ("A person of ordinary skill in the aircraft vane art simply would not find a 1919 reference about broken blades in a pugging mill reasonably pertinent to this problem."); *In re Butera*, 1 F.3d 1252, 1253, 28 USPQ2d 1399, 1400 (Fed. Cir. 1993) ("Butera's design is for air fresheners and insect repellents, while Hodge's is for metal ball anodes. The design of Hodge involves a different type of article from Butera's design and it is not analogous. One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode. Since Hodge is not analogous, the Board clearly erred in finding Hodge to be citable as prior art. Therefore there was no basis for rejecting Butera's claimed design as obvious."); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864, 26 USPQ2d 1767, 177 (Fed. Cir. 1993) ("Wang's SIMMs were designed to provide compact computer memory with minimum size, low cost, easy repairability, and easy expandability. In contrast, the Allen-Bradley patent relates to a memory circuit for a larger, more costly industrial controller. SRAMs were used by Allen-Bradley because of their intended industrial environment. According to Dr. Frey, size was not a consideration in the Allen-Bradley work. Thus, there is substantial evidence in the record to support a finding that the Allen-Bradley prior art is not reasonably pertinent and is not analogous.").

exhalation valve that opens and closes in cadence with a person's breathing, which is about 20 to 60 cycles per minute. And internal combustion engines, of course, operate at extraordinarily higher temperatures and pressures than a person's exhalation breath and are not powered by a person's lungs but by gasoline combustion. Further, McKim's valve is used for intake while the applicants' valve is used for exhaust.

A summary of the pertinent facts in *In re Clay* are provided below for ease of reference:

In re Clay	**Result: reference not analogous**					
	Description	***Problem to be Solved***	***Purpose***	***Operating Conditions***	***Similarities***	***Differences***
Clay	use of gel to displace liquid product from tank dead volume	preventing loss of stored product to tank dead volume	to displace liquid product from dead tank volume	• subterranean rock • high temps (115°C) and bore pressures	both used in petroleum industry	different purposes and operating under different temperatures and pressures
Prior Art Sydansk	use of gel to fill anomalies in natural oil-bearing conditions	recovering oil from rock	to channel flow in a desired direction	• made storage tank • ambient temp and pressure		
In re Japuntich et al.	**Result: not yet decided**					
Applicants' Invention	use of a new flapper-style exhalation valve in a filtering face mask	keeping valve closed under any orientation while allowing low pressure drop during an exhalation	to allow valve to open easier during an exhalation but remain closed under neutral conditions	• exhale valve on face mask body • body temperatures • low pressures • cadence of person's breathing	both relate to valves	different valves (intake v. exhaust), and different purposes and operating under different temperatures, pressures, and speeds
McKim	use of new reed intake valve in a two-stroke engine	stopping flutter or bounce of reed valve while operating under high RPM conditions	to eliminate float or bounce of valve reed to improve power and efficiency of engine	• intake valve on 2-cycle engine • high temps • high pressure • high speeds (10-12,000 rpms)		

2. McKim Does Not Describe a Flexible Flap

Even if McKim is found to be an analogous reference, a person of ordinary skill still would not have been led to applicants' invention because the structure of the reed valve disclosed in McKim would not answer the required properties of applicants' valve. As such, there would be no expectation, on the part of a person of ordinary skill, that McKim's teachings would be suitable for use on an exhalation valve.

There is no evidence that the McKim reed valve can demonstrate the required flexibility of applicant' flexible flap. Applicants have defined the term "flexible" to mean that "the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever, exposed to

gravity, and viewed from a side elevation (see, e.g., Fig. 6)."[5] The flap that is described in McKim is made of "spring sheet material, such as, for example, shim stock" (column 1, lines 59-61). McKim therefore is not describing a flexible flap that would be suitable for use in an exhalation valve.[6] This fact is confirmed by Richard Betts, a person skilled in the art of two-cycle engines:

> Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

Declaration of Richard Betts, paragraph 5 (December 7, 2001) (Exhibit E). Because McKim's valve reed is so structurally different — namely, so much stiffer than — the flexible flap that is used in applicants' invention, there would be no reason to expect — and there is no evidence in this record to indicate otherwise — that McKim's method of mounting its stiff valve reed would be suitable for use with a flexible flap of an exhalation valve. As stated by Betts in his Declaration, if secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation." Further, the conditions under which the McKim reed valve operates (high pressure, high temperatures, 10,000 or so cycles per minute) are so remarkably different from the conditions under which an exhalation valve operates (lung pressure, exhaled air temperatures, and breathing cycles of 20-60 per minute), that there can be no expectation that any structure described in McKim would be suitable in an invention like the one under consideration here. Thus, the

[5] Applicants' specification at page 7, lines 11-14.

[6] In an interview held with Examiner Lewis and the SPE Examiner Weiss in another continuation application in this series, Examiner Weiss agreed with applicants' attorney that a reed valve in a 2-cycle engine would not be flexible like the flap of the present invention.

mounting requirements for the McKim cannot so easily be transferred to an exhalation valve like Simpson's without some clear teaching or suggestion to do so.

3. No Evidence of Teaching of Suggestion to Combine McKim with Simpson

The record is devoid of any teaching, suggestion, or motivation to combine the pertinent teachings of Simpson and McKim. As the Board is also aware, an obviousness rejection cannot be sustained, based on a combination of references, without any evidence of why a person of ordinary skill would have been motivated to combine the pertinent teachings.[7] The suggestion to make the combination must come from the prior art.[8] It is not enough to simply identify each claimed element in the prior art.[9] "The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."[10]

Simpson's teachings are mainly concerned with producing a face mask that is in the shape of a pouch and that has an exhalation valve. Simpson's valve teachings are not concerned so much with showing how to make a low pressure drop valve that can remain closed under a variety of orientations as they are concerned with simply illustrating alternative valves that could be used on its pouch-shaped mask. And McKim's teachings are for providing a curved intake reed valve seat on a 2-cycle gasoline engine to reduce float or bounce. Nonetheless, the Examiner stated in the Final Office Action mailed May 7, 2003, that "[i]t would have been obvious to modify the flexible valve flap and seat of Simpson et al. (fig. 2) to be curved because it would have provided for quick seating, in an effective manner and without float or bounce after each opening as taught by McKim." **The Examiner, however, has not cited any authority for his view that eliminating float or bounce would have been a problem that persons skilled in the art of designing exhalation valves would have sought to overcome.** Without such authority, the Examiner's reasons for making the combination appear to be wholly based on subjective belief. As the Board

[7] *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) ("When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.").
[8] *In re Beattie*, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) ("The question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.").
[9] *Rouffet* at 1457. ("If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability.").

is aware, subjective beliefs cannot provide a proper evidentiary basis for sustaining a rejection based on a combination of references.[11] The burden showing evidence of a teaching or suggestion to combine therefore has not been met. Although not necessary to overcome the rejection, applicants have nonetheless responded to this unsupported position by furnishing testimony of an expert in the field of exhalation valves, John Bowers. Bowers states that "under the airflows and pressure drops that are encountered in the filtering face mask, 'bounce or float' is not an occurring event or problem that investigators in the exhalation valve art need to deal with." Thus, the "bounce or float" motivation cited in the Office Action for combining the two references does not exist, and the burden of supplying the record with evidence of a suggestion to combine has not been satisfied.

In response to applicants' arguments, the Examiner opines that the combination is proper because "[t]he mounting of flapper valves in the respirator art by clamping a stationary portion of the flap in a different plane than a sealing surface (i.e. seat) resulting in a curved configuration which physically biases a free end of the valve to a closed position is well known (see fig. 3 of Simpson et al.)." In support of this "well known" technology, the Examiner cites the prior art to Matheson (cited but not applied) U.S. Patent 2,999,498, fig. 8 and col. 1, lines 38-46." Although mounting the flap in a different plane than the sealing surface may be known as shown in the '498 patent to Matheson, this teaching nonetheless does not present evidence of a teaching or suggestion to combine the Simpson and McKim references. Matheson is a reference that resides in the respiratory field like the present invention. This document does not state that disclosures pertaining to a reed valve for a two cycle engine may be used to modify an exhalation valve in the respiratory art. Further, the Matheson document also provides very good evidence of nonobviousness because it too does not illustrate a construction where the flap is curved and is biased towards the seal surface. For ease of reference, applicants reproduce Figure 8 of Matheson below:

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[10] *In re Lee*, 61 USPQ 1431, 1433 (Fed. Cir. 2002).

[11] *See, Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation" would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.").

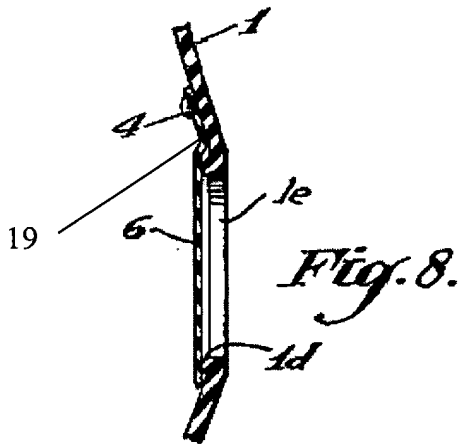

Fig. 8.

As shown, the Matheson valve has a "kink" in it at the location identified by applicants' attorney using numeral 19. This "kinked" portion would not cause the free portion of the flap to be pressed towards the seal surface so that it may reside closed under any orientation of the valve. Indeed, the Matheson patent indicates that its valve requires gravity to keep the flap closed:

> An important feature of suspending diaphragms 6 and 7 from the top only without further support along the marginal portions is that gravity will assist in keeping the diaphragms in their normal downward and seated positions as shown in Fig. 8.[12]

Further, inhalation valves, unlike exhalation valves, close during an exhalation in response to the exhalation pressure. And air that passes through the exhalation valve must first pass through the filtration media. Therefore, it is not important that a pre-stress is placed on the valve. The valve closes forcibly when a wearer exhales (see the '498 patent to Matheson at column 4, lines 1-8).

4. Evidence of Record Suggests Combination is Not Proper

The Simpson and McKim documents each present very good evidence of a lack of motivation to combine their respective teachings. The McKim technology was known to persons of ordinary skill before the Simpson publication. Nonetheless, Simpson did not employ the McKim technology in its flapper-style exhalation valve, even though Simpson and McKim both disclose flapper-style valves (albeit in entirely different fields). If the use of a curved flexible flap, and the particular structure necessary for creating that curvature and causing the flap to be pressed towards the seal surface, would have been obvious to a person of ordinary skill in making a flapper-style

[12] See the '498 patent to Matheson at column 2, lines 53-57.

exhalation valve, you would have expected a person skilled in the exhalation valve art to have used that technology in a valve like Simpson's.

The Board should notice that a very long time has passed since McKim's publication in 1962 and its disclosure of a curved flapper-style valve, but that particular technology did not find its way into use in the exhalation valve art at any point over this time span. If this aspect of the applicants' invention would have been obvious to a person of ordinary skill, then the skilled artisan in the respirator art would have been expected to employ it sometime within those years. A prolonged existence of unused technology provides very good evidence of nonobviousness.[13] Simpson, which was published almost 20 years after McKim and filed more than about 12 years before the effective filing date of the present application, also did not use this technology or find it to have been obvious. Nor did any other investigator in the filtering face mask art, either prior to or after Simpson (but before applicants' invention). Thus, the prior knowledge of the McKim technology and the long time that has elapsed since McKim's first publication, coupled with the failure to use this technology in a flapper valve system, presents very good evidence that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.[14]

In addition, Simpson, while recognizing that its valve may leak, suggests using an "antechamber" as a solution (p. 1, lines 58-64). Simpson does not suggest modifying this valve in the manner described by applicants. This presents very good evidence of the non-obviousness of the combination. And, to the extent that the Simpson valve does not remain closed under any orientation, this fact presents further evidence of nonobviousness.[15] As the record presently stands, therefore, only applicants describe a low pressure drop, cantilevered valve that is capable of sealing

[13] *See Al-Site Corp. v. Opti-Ray Inc.*, 28 USPQ2d 1915, 1922 (E.D.N.Y. 1993) ("Second, the prior art existed for many years and yet those skilled in the art never created a hanger mechanism comparable to Al-Site's patented invention. See *id.* at 1577."); see also, *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1604-05 (Fed. Cir. 1987) ("We cannot see why the district court's first set of findings did not require a conclusion that Caveney's inventions, which had for years escaped others who sought them, "would not have been obvious" under § 103; nor why Panduit and Dennison wasted research resources for years if Caveney's inventions were obvious to all throughout those years; nor how the prior art made Caveney's eminently successful inventions obvious to the court in 1984 when it had not made them obvious to skilled engineers (each more skilled than the 'ordinary mechanic' referred to in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 261, 13 L.Ed. 683 (1851)) who had been designing unsuccessful or far less successful cable ties for years when Caveney's inventions were made in the 1960's.").

[14] *See In re Ehringer*, 146 USPQ 31, 37, CCPA (1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag *thoriated* tungsten filament or any way of producing it.").

effectively under any orientation. Applicants' teachings, of course, cannot be properly used against them to reject their own invention. Accordingly, until sound evidence is placed in the record, the present combination cannot be properly sustained.

5. Prior Art Fails to Suggest Advantage of Applicants' Invention

An invention's advantages must be considered under the "invention as whole" concept set forth in 35 USC § 103.[16] Advantages that are not appreciated by the prior art also provide very good evidence of nonobviousness.[17] In the present case, applicants' invention possesses the benefit of achieving a low pressure drop valve while also preventing the influx of contaminants through the valve under any orientation. The Simpson valve, however, only protects the wearer at the most critical time — during an inhalation. When a wearer of either mask inhales, the flap becomes firmly pressed against the seal surface. But when the wearer is neither inhaling nor exhaling, and has their head tilted downward, gravity can cause the flap to droop away from the seal surface. Simpson's valve therefore may allow contaminants to enter the mask interior in this instance. To counter this problem, Simpson suggests the use of an antechamber and mounts its valve on the top of the mask body so that gravity can be used to keep the flap closed under neutral conditions. If the valve was mounted to the underside of the mask, the flap would dangle away from the seal surface. The Simpson valve, unlike applicants' invention, therefore, have limited suitable mounting positions on the mask body when considering the need to halt contaminant influx under neutral conditions. But even if either valve was mounted to the top of the mask body to take advantage of gravity for this purpose, they, still could allow contaminants to enter the mask interior when the user fully tilts their head downward. Further Simpson does not teach or suggest valves that have a pre-load on the flap. As such, these valves can remain open when moisture of saliva causes the flap to stick to another surface like a valve cover.

Applicants teach persons of ordinary skill how to make a low pressure drop flapper-style exhalation valve that will preclude contaminant influx under all orientations of the mask. Applicants achieve this through the use of a single flexible flap that has one free portion, one stationary portion, and a peripheral edge, where the peripheral edge has a stationary and free

[15] *In re Dien,* 152 USPQ 550, 551 (CCPA 1967) ("The mere existence ... of an unsatisfactory process and the attendant incentive to seek improvement do no negative patentability.').
[16] *In re Papesch,* 137 USPQ 43 (CCPA 1963).
[17] *See, e.g., In re Fine,* 5 USPQ2d 1596, 1600 (Fed. Cir. 1989) (Advantages not appreciated by prior art.).

segments that are associated, respectively, with the stationary and free portions of the flap, and through imparting a curvature to the flexible flap and causing the flap to be pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice. Applicants' valve also does not have to be disposed on the top side of the mask, and there is little risk that the flap will get stuck in the open position. Applicants' invention thus enables the valve to be disposed on the mask directly in the path of the exhale flow stream — that is, centered on the front of the mask directly in front of where the wearer's mouth would be when the mask is worn (see Fig. 1) — so that the valve can use the full momentum of the exhaled air stream to lift the flap from the seal surface. This encourages a substantially larger percentage of air to pass rapidly through the exhalation valve. And may allow an aspiration effect to occur, which further improves wearer comfort.[18] The aspiration effect is a truly remarkable achievement since it allows cool ambient air to be drawn into the mask interior during an exhalation.

As indicated in paragraphs 15 and 16 of the Bowers Declaration (Exhibit C), the Simpson flap would droop open when the wearer tilts their head downward:

> My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.
>
> The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

The failure of Simpson to appreciate the benefits of applicants' invention and instead teach a more deficient construction further establishes the nonobviousness of applicants' invention. McKim, of course, does not address these benefits to the slightest degree because it is a reference that resides in an entirely different field and deals with entirely different problems, which

[18] *See* applicants' specification at pp. 20-23.

problems are encountered under entirely different conditions. In short, the prior art does not teach or suggest the construction of applicants' valve, and it does not appreciate the benefits that that construction invention can provide. Under such circumstances, Simpson and McKim would not have rendered applicants' invention obvious to a person of ordinary skill within the meaning of 35 USC § 103.

6. Evidence of Copying Shows Nonobviousness

The copying of the technology of applicants' invention shortly after its publication further establishes its non-obviousness. As the Board is aware, the reviewing courts have relied on evidence of copying to find an invention to be not obvious to a person of ordinary skill.[19] For example, in *Specialty Composites v. Cabot Corporation,*[20] the Federal Circuit stated that "[c]opying the claimed invention, rather than one in the public domain, is indicative of unobviousness."[21] Secondary considerations like copying must always be considered in connection with an obviousness determination.[22]

An examination of this article reveals a cantilevered flexible flap that is curved and is pressed towards the seal surface in a substantial abutting relationship with it. This product is described in U.S. Patent 6,047,698 to Magidson et al., which was filed on August 20, 1998, after applicants' invention was publicly disclosed. But Moldex' earlier reveals that button-style valves were used on Moldex' filtering face masks (see U.S. Patent 4,873,972). And the more recent '698 Magidson patent (which describes the Exhibit F valve) states the benefits of using the technology claimed in this patent application:

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[19] See e.g., *Avia Group International, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1564, 7 USPQ2d 1548, 1554 (Fed. Cir. 1988) (Copying is additional evidence of nonobviousness."); *Diversitech Corp. v. Century Steps, Inc.* 850 F.2d 675, 679, 7 USPQ2d 1315, 1319 (Fed. Cir. 1988) ("Copying is an indicium of nonobviousness, and is to be given proper weight."); *Dow Chemical Co. v. American Cyanamid Co.*, 816 F. 2d 617, 622, 2 USPQ2d 1350, 1355 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 849 (1987) (the conclusion that the claimed invention would not have been obvious is supported by evidence of commercial success and acts of the infringer in trying but failing to "develop the claimed invention and [then copying] it instead"); *Windsurfing International, Inc. v. AMF Inc.*, 782 F.2d 995, 1000, 228 USPQ 562, 565 (Fed. Cir. 1986), ("copying the claimed invention, rather than one within the public domain, is indicative of non-obviousness").

[20] 6 USPQ2d 1601, Fed. Cir. 1988.

[21] *Id.* at 1608.

[22] *In re Sernaker*, 217 USPQ 1, 7 (Fed. Cir. 1983) ("If, however, a patent applicant properly presents evidence relating to these secondary considerations, the board must always consider such evidence in connection with the determination of obviousness."); see also *W.L. Gore & Assoc. Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983) ("As discussed more fully below, the district court erred in specifically declining to consider the objective evidence of nonobviousness."); Manual of Patent Examining Procedure 2100-90 (Feb. 2000).

> The valve member 16 includes an off center arm 24 which cooperates with a shelf portion 26, located within the valve seat 22, to lock the flexible flap 20 off center in position within the valve 14 when the two half members 16 and 18 are closed, as shown by arrow 28, around a hinge portion 30.

(Column 2, lines 15-21). The '698 Moldex patent goes on to state that the flap is pushed into sealing engagement with the valve seat when a fluid is not passing through the orifice. Moldex illustrates the technology in Figs. 3 and 4:

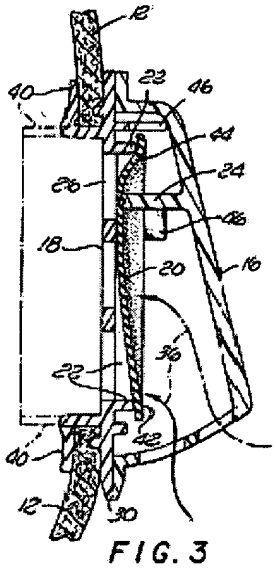

FIG. 3

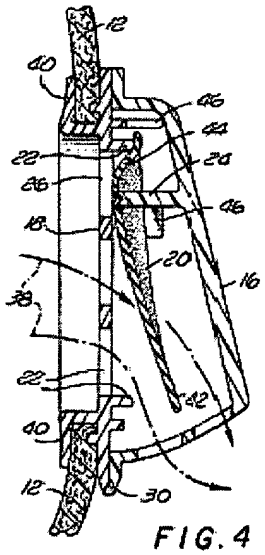

FIG. 4

Another product of similar structure, which also was introduced after the publication of applicants' invention has been sold by Survivair (Exhibit G).

The use of the technology of applicants' invention by other respiratory product manufacturers after publication of applicants' invention provides very good evidence that the invention would not have been obvious to a person of ordinary skill. Although Simpson's teachings had been known for many years before applicants' filing date, there is no evidence that any competitor had previously introduced a product that is similar to the exhalation valve that is described and claimed in the present application. The introduction of such products after the publication of the technology of applicants' invention, however, further establishes that person's skilled in the filtering face mask art surely did not find obvious the subject matter of applicants' invention.

Issue 3 - Rejection of Claims 60-63

Although U.S. Patent 812,706 to Warbasse (published in 1906) has been referenced for teaching a valve cover that has a fluid-impermeable ceiling that increases in height in the direction of a flexible flap from a first end to the second end, Warbasse does not suggest the use of its valve cover on an exhalation valve that is used in a filtering face mask that is adapted to fit over the nose and mouth of a person. Warbasse describes a device that is placed over a person's nose and is connected to a supply line tube 16. No teaching or suggestion has been identified, which would have motivated a person of ordinary skill to use Warbasse's hood element 11 in the Simpson valve shown in Figure 2. The Examiner indicates that "it would have been obvious to modify the valve (figure 2) of Simpson et al. to provide a valve in this (fig. 2) to provide a valve cover because it would have provided a means for protecting the valve flap (12), controlling the extent of movement of the valve flap, controlling the direction of fluid flow exiting the mask via the valve as taught by Warbasse." Although there may be a variety of reasons for using a valve cover on the valve shown in Simpson, *the Examiner has not yet identified any particular suggestion of why a person of ordinary skill would have selected the hood element 11 in Warbasse's nose device for use on the exhalation valve shown in Figure 2 of Simpson.* As the Board is aware, the United States Patent and Trademark Office has the burden of providing *evidence* that shows why a person or ordinary skill would have combined the teachings in two different references. Mere conclusory statements generated by the Examiner do not qualify as evidence. In this regard, the Board's attention is again directed to *In re Lee* where the Federal Circuit explained that the motivation to combine references is a factual question that cannot be resolved on subjective beliefs of unknown authority.[23]

The Examiner states that the reasons for combining Warbasse with Simpson are taught in Warbasse (see page 12 of the Final Office Action). *But a review of Warbasse reveals that none of these reasons can be found anywhere in the document.* Some of these reasons, however, can be found in applicants' specification. For example, applicants state that the exhalation valve, "can be provided with a valve cover to protect the flexible flap" (see applicants specification, page 14, lines 33-35). Applicants also explain that the valve cover can allow the exhaled air to be "directed downwards to prevent fogging of the wearer's eyewear" (see applicants' specification at page 15, lines 5-8). It is, of course, improper to use applicants teachings against them in attempting to

establish that a person of ordinary skill would have been led to the combination of references.[24] The record therefore does not establish why a person of ordinary skill would have been motivated, in particular, to use Warbasse's hood element 11 on Simpson's valve over any of the multitudes of value covers that have been previously described in the art.

The Braun patent adds little or nothing to the disclosure that is lacking in Simpson and McKim with respect to claims 60-63. The Braun patent does not teach or suggest a valve cover that has a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end. To the contrary, *Braun does not even teach or suggest a fluid-impermeable ceiling. Braun only describes a grill 25, and this grill 25 does not have a fluid-impermeable ceiling that increases in height* in the direction of the flexible flap from its first end to its second end. To the contrary, the grill 25 is located closer to the free end of the flap 24 relative to its fixed portion located at 19. Under such circumstances, Braun teaches away from applicants' invention and also provides very good evidence that the subject matter of claims 60-63 would not have been obvious to a person of ordinary skill.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application under 35 USC § 103(a). Please reverse the decision below.

Respectfully submitted,

November 6, 2003
Date

By: _____
Karl G. Hanson, Reg. No.: 32,900
Telephone No.: (651) 736-7776

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833

Enclosed Exhibits:
A - McGinley Affidavit
B - Gerson Mask
C - Bowers Declaration

[23] *See In re Lee*, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002) ("This factual question of motivation [to combine the references] is material to patentability and could not be resolved on subjective belief and unknown authority.").
[24] *In re Lee*, 61 USPQ2d at 1434 ("It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to '[use] that which the inventor taught against its teacher.'"; *see also, W.L. Gore v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-313 (Fed. Cir. 1983).

D - Fabin Affidavit
E - Betts Declaration
F - Moldex Mask
G - Survivair Mask

APPENDIX

33. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface;

(ii) an orifice that is circumscribed by the seal surface; and

(iii) cross members that extend across the orifice to create a plurality of openings within the orifice; and

(2) a single flexible flap that has a fixed portion and only one free portion and first and second opposing ends, the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during an exhalation, and the second end being associated with the only one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces are applied to it, but the flexible flap when secured to the valve seat at its fixed portion has a curved profile when viewed from a side elevation and is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice.

35. The filtering face mask of claim 33, wherein the valve seat is made from a relatively light-weight plastic that is molded into an integral one-piece body.

36. The filtering face mask of claim 35, wherein the valve seat has been made by an injection molding technique.

37. The filtering face mask of claim 33, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface.

38. The filtering face mask of claim 37, wherein the flexible flap is elastomeric and is resistant to permanent set and creep.

39. The filtering face mask of claim 37, wherein the flexible flap is made from an elastomeric rubber.

40. The filtering face mask of claim 33, wherein the flexible flap has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C.

41. The filtering face mask of claim 40, wherein the flexible flap provides a leak-free seal according to the standards set forth in 30 C.F.R. § 11.183-2, July 1, 1991.

42. The filtering face mask of claim 33, wherein the flexible flap is made from a crosslinked polyisoprene.

43. The filtering face mask of claim 33, wherein the flexible flap has a Shore A hardness of about 30 to 50.

44. The filtering face mask of claim 33, wherein the flexible flap has a generally uniform thickness of about 0.2 to 0.8 millimeters.

45. The filtering face mask of claim 44, wherein the flexible flap has a generally uniform thickness of about 0.3 to 0.6 millimeters.

46. The filtering face mask of claim 45, wherein the flexible flap has a generally uniform thickness of about 0.35 to 0.45 millimeters.

47. The filtering face mask of claim 33, wherein the one free portion of the flexible flap has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface.

48. The filtering face mask of claim 47, wherein the flexible flap is greater than one centimeter wide.

49. The filtering face mask of claim 48, wherein the flexible flap is 1.2 to 3 centimeters wide and is about 1 to 4 centimeters long.

50. The filtering face mask of claim 33, wherein the fixed portion of the flexible flap is about 10 to 25 percent of the total circumferential edge of the flexible flap, with the remaining 75 to 90 percent being free to be lifted from the seal surface.

51. The filtering face mask of claim 33, wherein the valve seat includes a flange that provides a surface onto which the exhalation valve can be secured to the mask body, and wherein the flange extends 360 degrees around the valve seat where the valve seat is mounted to the mask body.

52. The filtering face mask of claim 33, wherein the flexible flap is positioned on the valve such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

53. The filtering face mask of claim 33, wherein the mask body is cup-shaped and comprises (1) at least one shaping layer for providing structure to the mask, and (2) a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

54. The filtering face mask of claim 33, wherein a high percentage of the exhaled air is purged through the exhalation valve.

55. The filtering face mask of claim 33, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

56. The filtering face mask of claim 55, wherein at least 73 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

57. The filtering face mask of claim 33, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth, and wherein the flexible flap is mounted to the valve seat in cantilever fashion.

60. The filtering face mask of claim 33, which mask further comprises:

a valve cover that is disposed over the valve seat and that comprises:

(i) an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation;

(ii) a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end; and

(iii) cross members that are disposed within the opening of the valve cover.

61. The filtering face mask of claim 60, wherein the opening in the valve cover is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

62. The filtering face mask of claim 60, wherein the valve cover and its opening direct exhaled fluid flow downwards when the mask is worn on a person.

63. The filtering face mask of claim 62, wherein the valve cover has fluid-impermeable sidewalls.

66. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is circumscribed by the seal surface;

(2) a single flexible flap that is secured to the valve seat and that has a non-centrally disposed stationary portion and a free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the non-central stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free portion also being located below the non-central stationary portion when the filtering face mask is worn on a person, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces applied to it but when secured to the valve seat and viewed without a fluid passing through the orifice, the flexible flap (i) has a curved profile when viewed from a side elevation in its secured position on the valve seat and (ii) is pressed towards the seal surface in an abutting relationship therewith.

67. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is surrounded by the seal surface when viewing the valve seat from the front;

(2) a single flexible flap that is secured to the valve seat and that has a non-centrally disposed stationary portion and only one free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the non-central stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the only one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the only one free portion also being located below the non-central stationary portion when the filtering face mask is worn on a person, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces applied to it but when secured to the valve seat and viewed without a fluid passing through the orifice, the single flexible flap (i) has a curved profile when viewed from a side elevation in its secured position on the valve seat and (ii) is pressed towards the seal surface in an abutting relationship therewith.

68. The filtering face mask of claim 67, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface.

69. The filtering face mask of claim 67, wherein the flexible flap is elastomeric and is resistant to permanent set and creep.

70. The filtering face mask of claim 67, wherein the flexible flap is made from an elastomeric rubber that has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C, and wherein the flexible flap provides a leak-free seal according to the standards set forth in 30 C.F.R. § 11.183-2, July 1, 1991.

71. The filtering face mask of claim 70, wherein the flexible flap is made from a crosslinked polyisoprene.

72. The filtering face mask of claim 67, wherein the flexible flap has a Shore A hardness of about 30 to 50, and has a generally uniform thickness of about 0.3 to 0.6 millimeters.

73. The filtering face mask of claim 67, wherein the one free portion of the flexible flap has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface, and wherein the flexible flap is 1.2 to 3 centimeters wide and is about 1 to 4 centimeters long.

74. The filtering face mask of claim 67, wherein the fixed portion of the flexible flap is about 10 to 25 percent of the total circumferential edge of the flexible flap, with the remaining 75 to 90 percent being free to be lifted from the seal surface.

75. The filtering face mask of claim 67, wherein the flexible flap is positioned on the valve such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

76. The filtering face mask of claim 67, wherein the mask body is cup-shaped and comprises at least one layer for providing structure to the mask and a filtration layer, the at least one structure-providing layer being located outside of the filtration layer.

77. The filtering face mask of claim 67, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

78. The filtering face mask of claim 67, wherein at least 73 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

79. The filtering face mask of claim 67, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth, and wherein the flexible flap is mounted to the valve seat in cantilever fashion.

80. The filtering face mask of claim 67, wherein the shape of the orifice does not wholly correspond to the shape of the seal surface.

81. A filtering face mask that comprises:

(a) a substantially cup-shaped mask body that is fluid permeable, contains a layer of filter media, and is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is surrounded by the seal surface when viewing the valve seat from the front;

(2) a single flexible flap that is secured to the valve seat and that has a non-centrally disposed stationary portion and only one free portion and a peripheral edge that includes a free segment, the non-centrally disposed stationary portion of the flap remaining essentially stationary during an exhalation, and the free segment of the peripheral edge being associated with the only one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces applied to it but when secured to the valve seat and viewed when a fluid is not passing through the orifice, the single flexible flap (i) has a curved profile when viewed from a side elevation in its secured position on the valve seat and (ii) is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the mask.

82. The filtering face mask of claim 33, wherein the shape of the orifice does not wholly correspond to the shape of the seal surface.

83. The filtering face mask of claim 60, wherein the opening in the valve cover is at least the size of the orifice in the valve seat.

PATENT
Docket No.: 48317USA3C.014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL.

Serial No.: 08/240,877

Filed: May 11, 1994

For: UNIDIRECTIONAL FLUID VALVE

Group Art Unit: 3761

Examiner: A. Lewis

AFFIDAVIT OF BRIAN S. MCGINLEY

I, Brian S. McGinley, being duly sworn, state as follows:

1. I presently hold the position of Product Marketing Manager in the Occupational Health & Environmental Safety Products Division (OH&ESD) at the 3M Company, St. Paul, Minnesota. In this position I am responsible for pricing, promotion, packaging, and positioning of 3M OH&ESD respiratory products.

2. I have been working in the respiratory field for the past 18 years and am very familiar with the art pertaining to personal respiratory protection devices, including filtering face masks that are worn over the nose and mouth of a person and that use exhalation valves to purge warm, moist exhaled air from the mask interior.

3. I am familiar with the subject matter of the above-captioned patent application, and I have reviewed the claims pending in this application and understand their scope and content.

4. I have witnessed the evolution of the art in respiratory products, in particular the evolution of the exhalation valve art on filtering face masks. On information and belief, I believe that the following sequence of events has occurred in this field:

a. Before May 29, 1992, 3M invented a filtering face mask that comprised a mask body and an exhalation valve. The mask body was adapted to fit over the nose and mouth of a person and had a filtering layer for filtering air that passed through the mask body.

EXHIBIT A

The exhalation valve was attached to the mask body, and it comprised a valve seat that included an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also had a single flexible flap that had a stationary portion, one free portion, and a circumferential edge that included stationary and free segments. The stationary segment of the circumferential edge was associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation, and the free segment of the circumferential edge was associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge was disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

This filtering face mask differed from known commercial products in that the flexible flap was noncentrally secured to the valve seat (relative to the orifice) at the flap retaining surface, and the flap retaining surface and seal surface were nonaligned and positioned relative to each other to allow for a cross-sectional curvature of the one free portion of the flexible flap when viewed from the side in a closed position. The nonalignment and relative positioning of the flap-retaining surface and the seal surface also allowed for the free portion of the flexible flap to be pressed towards the seal surface when a fluid was not passing through the orifice and to allow for the free portion of the flexible flap to be lifted from the seal surface during an exhalation.

b. On December 9, 1993, the filtering face mask described in paragraph 4.a was first published in International Publication WO 93/24181. This new filtering face mask was also published in U.S. Patent 5,325,892 on July 5, 1994.

c. In 1993, OH&ESD introduced in Europe its filtering face mask product that had a valve that included the structure described above in paragraph 4a. An Example of this kind of valve is attached to this Affidavit as Exhibit A. This product meets all of the limitations of the broadest claim pending in the above-captioned application (claim 78).

d. Before 3M's publication and introduction of the new filtering face mask product referred to in paragraphs 4.a and 4.b, it is my understanding and recollection, that essentially all previous commercial filtering face mask products had used an exhalation valve that had a centrally-mounted flap. Known valves that had centrally-mounted flaps

mainly had a circular flap member that was mounted to a valve seat through a central stake or button. These valves are commonly referred to in the art as "button-style" valves and had been used on 3M commercial filtering face masks for approximately 13 years before 3M's original filing date of the flapper-style valve of claim 78. Examples of button-style valves are shown in U.K. Patent Application 2,072,516A (Fig. 3) published 1981, U.S. Patent 2,895,472 (Fig. 5) published 1956, U.S. Patent 2,230,770 (Figs. 11-14, 27-29) published 1940, and U.S. Patent 4,630,604 (Figs. 1, 2 and 4-5) published 1986. Another centrally mounted valve — although not nearly as common — had been (and continues to be) sold by OH&ESD in Europe and is described in U.S. Patent 4,934,362 to Braun. This latter product is not referred to as a button-style valve. But the flap is centrally-mounted to the valve seat by a central bridge.

e. In 1995, Racal Health & Safety introduced in the United States a filtering mask that had a flapper-style valve. This new Racal mask had an exhalation valve that was similar to the structure and function of the flapper valve product that was previously published and introduced by OH&ESD and claimed in the above-caption application. A sample of this product is attached to this Affidavit as Exhibit B. This valve is also shown and described in Racal's U.S. Patent No. 5,687,767. Like the invention claimed in the present application, the Racal product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

f. Around approximately late 1998, Moldex Metric Inc. introduced in the United States a filtering face mask that also had a flapper-style valve. This new Moldex mask had an exhalation valve that was similar to the structure and function of the flapper valve

product that was previously published and introduced by OH&ESD and claimed in the above-captioned application. Moldex Metric sells this valve under the trademark Ventex™. A sample of this product is attached to this Affidavit as Exhibit C. This valve is also described in Moldex's U.S. Patent No. 6,047,698, filed August 20, 1998. Like the invention claimed in the present application, the Moldex product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

g. In approximately 1999, Ever Green Co. Ltd. of Korea introduced a filtration face mask product in that country, which mask was similar in structure and function to the respiratory product previously published and introduced by OH&ESD and claimed in the above-captioned application. A sample of their product is attached to this Affidavit as Exhibit D. Like the invention claimed in the present application, the Korean product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

h. In approximately March of 2000, Louis M. Gerson Company introduced in the United States a filtering face mask product that was similar in structure and function to the filtering face mask previously published and introduced by OH&ESD and claimed in the above-captioned application in paragraphs 4. a-c above). An example of this product is attached to this Affidavit as Exhibit E. Like the invention claimed in the present application, the Gerson product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

i. In approximately November of 2000, Survivair (division of Bacou USA Safety Inc.) introduced a filtering face mask product that had an exhalation valve similar in structure and function to the exhalation valve previously published and introduced by OH&ESD and claimed in the above-captioned application. A sample of this product is attached to this Affidavit as Exhibit F. Like the invention claimed in the present application, the Survivair product has an exhalation valve that includes a valve seat and a single flexible flap. The valve seat has an orifice, a seal surface surrounding the orifice, and a flap retaining surface. The exhalation valve also has a single flexible flap that has a stationary portion and one free portion and a circumferential edge that includes stationary and free segments. The stationary segment of the circumferential edge is associated with the stationary portion of the flexible flap so as to remain in substantially the same position during an exhalation. The free segment of the circumferential edge is associated with the one free portion of the flexible flap so as to be movable during an exhalation. The free segment of the circumferential edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position.

5. The public disclosure and introduction of the OH&ESD filtration face mask product of the above-captioned invention — followed closely by five competitive products that share the same new technology previously disclosed and claimed in the above-captioned application, and coupled with the fact that no previous filtering face mask product used this technology but primarily relied on centrally-mounted flap valve technology, particularly button-style valves — lead me to the firm conclusion that the technology first created by OH&ESD and claimed in the present application was copied by each of these competitors.

Brian S. McGinley

Subscribed and sworn to before
me this 28th day of June, 2001.

Notary Public

SUSAN M. DACKO
NOTARY PUBLIC MINNESOTA
My Comm. Expires Jan. 31 2005

EXHIBIT B

Gerson Mask

Patent
Case No: 48317US014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
DANIEL A. JAPUNTICH ET AL.
Serial No.: 08/240,877
Filed: May 11, 1994
For: UNIDIRECTIONAL FLUID VALVE

Group Art Unit: 3761

Examiner: A. Lewis

DECLARATION OF JOHN L. BOWERS

I, John L. Bowers, state as follows:

2. I have been working in the respiratory field for about the past 15 years and am very familiar with the art pertaining to personal respiratory protection devices, including filtering face masks that are worn over the nose and mouth of a person and that use an exhalation valve to purge warm, moist, exhaled air from the mask interior.

3. I hold two U.S. patents in the respiratory field, including U.S. Patent 5,687,767 to Bowers, originally assigned to Racal Health & Safety Limited, England. This patent describes a unidirectional flapper-style fluid valve that is useful as an exhalation valve on a filtering face mask.

4. I am familiar with the subject matter of the above-captioned application.

5. I used to be an employee at Racal Health & Safety Limited prior to the acquisition of its assets by 3M. I worked at Racal for 9 years and had the title of operations and technical manager. In that position, I was responsible for health and safety product development, particularly for respiratory masks.

6. I presently hold the position of site manager in the Occupational Health & Environmental Safety Products Division (OH&ESD) at the 3M Company, 12-16 Bristol Road, Greenford Middlesex, England. In this position I am responsible for the day to day operation of the manufacturing and distribution centers for powered and supplied air respirators.

7. While working at Racal, I was assigned the responsibility to develop a new exhalation valve for its respiratory masks. Racal had a number of customer requests for a mask

EXHIBIT C

that had an exhalation valve to purge warm, moist air from the mask interior. In considering candidates for exhalation valves on our respiratory products, I initially looked at conventional button-style valves. These valves, however, were not selected for widespread commercialization of Racal face masks because the cracking pressure required to open the button-style valve was found to be relatively high. I found that the central pivoting point created an undesirably higher opening force.

8. As part of the process for designing a new valve, I examined the exhalation valve that was recently commercialized by 3M. This valve is described in U.S. Patent 5,325,892 to Japuntich et al. I not only examined an actual commercial embodiment of the 3M valve, but I also carefully reviewed the disclosure of the '892 3M patent.

9. My evaluation of the 3M valve showed a product that had better performance than the conventional button-style valves. This evaluation led me in pursuit of developing a flapper-style valve similar to the 3M valve. The valve that was ultimately designed by me for Racal was the flapper-style unidirectional fluid valve that is shown in U.S. Patent 5,687,767 to Bowers, and a sample of which is attached to this Declaration as Exhibit G. I sought to design a valve that would avoid infringement of the issued 3M '892 patent and would be patentable over its disclosure. The filtering face mask that was developed, which employed the new Racal valve that I developed, did possess some features similar to the 3M valve and borrowed technology learned from the 3M valve. In particular, I designed the exhalation valve for Racal so that the flexible flap of the Racal valve was secured non-centrally relative to the orifice and had a free portion that was pressed against the seal surface when a wearer was neither inhaling nor exhaling, and the flap had a curvature in the free portion when viewed from the side elevation in a closed position (although the Racal valve that I designed was also made to have a transverse curvature). The flap was also designed to have stationary and free portions with a circumferential or peripheral edge that had stationary and free segments, respectively. The flap was secured to the valve seat at the flap-retaining surface closer to the stationary segment of the peripheral edge than to the free segment. Other than the transverse curvature, the features described in the three previous sentences were present in the 3M valve and were discovered from my examination of the 3M product and the published '892 patent. The Racal valve thus was able

to remain closed under neutral conditions under any orientation, like the 3M valve, to prevent the influx of contaminants and was also able to open under a relatively small exhalation force.

10. I have also read U.K. Patent Application GB 2072516 to Simpson et al. (Simpson) and U.S. Patent 3,191,618 to McKim, and I do not believe that the combination of Simpson and McKim would have led a person of ordinary skill in the art to the present invention. In my view, the McKim patent is not pertinent to the subject matter sought to be patented in the above-captioned U.S. Patent Application Serial No. 08/240,877 and is not pertinent to the subject matter taught in Simpson.

11. My review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which could turn at speeds as possibly as high as 10,000 or 12,000 revolutions per minute (rpm). The reed valve described in McKim is indicated to be particularly suited for a high speed operation where opening and closing forces are large. McKim states these forces can cause the valve to bounce (an apparent elastic recoil from impact). The stated goals in McKim are full and rapid opening, quick and complete closing, and eliminating float and bounce.

12. The field of the above-captioned '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow warm, moist, exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves generally operate at normal room temperatures and pressures.

13. The field of endeavor for filtering face mask is very different from the field of endeavor of a reed valve that is used in a two-cycle engine. Exhalation valves for respirators operate under very different conditions from valves that are used in two-cycle engines and require notably different design parameters. The valve that is described in McKim has very rapid opening and closing requirements (thousands of openings and closings per minute) and operates under temperatures and pressures that differ substantially from the requirements of exhalation valves, which open and close under the much slower pace of a wearer's breathing and under temperatures and pressures that tend to vary only from the ambient to that exhibited by the wearer's exhaled air. Thus, persons of ordinary skill in the field of designing filtering face

masks, to the best of my knowledge and experience, do not find valves for two-cycle engines to be in their field of endeavor and therefore do not consult documents that describe valves for these engines when developing new respiratory products.

14. In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

15. My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior

when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

16. The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated this Tenth day of December, 2001.

John L. Bowers

Witness

Witness

STUART MILLER

Patent
Case No: 48317US014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
DANIEL A. JAPUNTICH ET AL.
Serial No.: 08/240,877
Filed: May 11, 1994
For: UNIDIRECTIONAL FLUID VALVE

Group Art Unit: 3761

Examiner: A. Lewis

AFFIDAVIT OF FRANK J. FABIN

I, Frank J. Fabin, being duly sworn, state as follows:

1. I presently hold the position Technical Manager for the Respirator Systems Business Unit of the Occupational Health and Environmental Safety Products Division (OHESD) at the 3M Company, St. Paul, Minnesota.

2. I received a Bachelors of Science degree in mechanical engineering from the University of Maryland in 1970. I also have received a Masters of Business Administration from the University of St. Thomas, St. Paul, Minnesota, in 1979.

3. I began work for the OHESD in 1977 as an engineer in division engineering. From 1981 to 1991, I worked in product automation and new product development for OHESD. During the period of 1990 and 1991, I was the action team leader for the development of an exhalation valve that resulted in an invention that is the subject matter of the above-captioned patent application. Before being the action team leader for this valve development assignment, I was also on the product development team for the respirator valve that was the subject of U.S. Patent 4,934,362 to Braun. From about 1992 to present, I have been the Technical Manager for the Respirator Systems Business Unit of the OHESD. In this capacity, I have overseen the development of positive pressure respirators and elastomeric face pieces and the components that are used on these products, including exhalation valves.

4. I have obtained about 4 issued U.S. patents for the OHESD since I began employment with this business unit.

5. I am familiar with the subject matter of U.S. patent application Serial No. 08/240,877.

EXHIBIT D

6. I understand that the Examiner has held the subject matter of claim 78 to be unpatentable based on the disclosures in U.K. patent application GB 2072516A to Simpson et al. (Simpson) and U.S. Patent 3,191,618 to McKim. I understand that the Examiner has concluded that "[i]t would have been obvious to modify the flexible flap and seat of Simpson et al. (fig. 2) to be curved because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (col. 1, lines 64-72)."

7. I have reviewed the Simpson and McKim patent disclosures, and I do not believe that a person of ordinary skill in the filtering face mask art would have combined the teachings of these references. I do not believe that a person of ordinary skill would be motivated to look at references in the valve art for gasoline engines for solutions to problems confronted in the filtering face mask field or the exhalation valve art field. I further do not believe that the subject matter of the McKim patent is pertinent to the subject matter described in Simpson. Nor do I believe that the McKim disclosure is pertinent to the subject matter sought to be patented in the above-captioned U.S. patent application Serial No. 08/240,877.

8. My review of the McKim patent reveals a curved seat reed valve that is suitable for use in high rpm two-cycle engines. The reed valve comprises a thin, normally flat, single thickness, springy, sheet material, which, when relieved of external stresses will lie flat, but which is flexed lengthwise to define a curve. The reed valve is disclosed to be made of a spring sheet material, such as, for example, shim stock. The reed valve is disclosed to bear throughout its length against a valve seat, with the seating bias at the free end of the reed being as great as, or greater than, that throughout the remainder of the reed. The reed valve is indicated to be designed to seat quickly, effectively, and without float or bounce after each opening. The patent indicates that the reed valve is adaptable for use within an extremely high-speed engine, for example, one that will turn at a speed on the order of 10,000 or 12,000 revolutions per minute or at more modest speeds of 5,000 to 6,000 rpms.

9. In my approximately 24 years of working in occupational health, I have not — nor am I aware of another person who works in this field who has — consulted a reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks.

10. Filtering face masks posses the problem of creating a warm, moist, high CO_2 content environment around the nose and mouth of a person who wears a filtering face mask. Investigators in this field have pursued a goal of purging from the mask interior the largest amount of fluid possible while using the least amount of energy. Investigators therefore have pursued the particular goal of designing exhalation valves that open easily in response to the exhalation pressure developed in the mask interior during an exhalation. Exhalation valves that open under minimal pressure allow the warm, moist high CO_2 content air, to be more easily removed from the mask interior and thus require the wearer to expend less energy to operate the valve over an extended period of time. Exhalation valves typically operate under ambient environmental conditions in response to exhalation pressures generated by the wearer. These conditions are remarkably different from the environment (for example, temperatures and pressures) under which a reed valve operates in a two-cycle gasoline engine. The flexible flaps that are used in exhalation valves do not deal with problems of float, or flutter from bounce in closing like the reed valves described by McKim. The opening and closing of an exhalation valve occurs in cadence with a wearer's breathing pace, which is orders of magnitude less than the high rpms under which gasoline engines operate at. For these reasons and others, persons of ordinary skill in the filtering face mask and exhalation valve art, as far as I am aware, do not examine documents that pertain to reed valves for two-cycle gasoline engines in designing filtering face masks and the exhalation valves that are used on them. Documents that describe reed valves for two-cycle gasoline engines are not in the field of endeavor of persons who design exhalation valves for filtering face masks.

11. The present invention was concerned with providing a filtering face mask that would not allow contaminants to enter the interior of the mask through the valve and would, at the same time, be comfortable to the wearer by displacing as large a percentage of exhaled air as possible through the exhalation valve with minimal effort. The present invention is concerned with "(1) minimizing exhalation pressure inside a filtering face mask, (2) purging a greater percentage of exhaled air through the exhalation valve (as opposed to having the exhaled air pass through the filter media), and under some circumstances (3) providing a negative pressure inside a filtering face mask during exhalation to create a net flow of cool, ambient air into the face mask." The art of reed valves for gasoline engines is not a source, to my knowledge, that has ever been consulted by persons who develop filtering face masks and the exhalation valves that are used on them. Nor

to my knowledge has the art for reed valves for gasoline engines ever been consulted to deal with the nature of the problems that were attempted to be solved by those who develop exhalation valves for filtering face masks. I am not aware of one instance where persons of ordinary skill in the filtering face mask or exhalation valve art has found reed valves for gasoline engines to be reasonably pertinent to problems that they encounter in the development of these products. In all of my years of working in this field, and in supervising others who work in this field, I have not seen one instance where a reference to a reed valve for a gasoline engine has been one that would have logically commended itself to the attention of an investigator in the field of developing filtering face masks or exhalation valves or would have been consulted to overcome problems that are confronted in the design of such products.

Frank J. Fabin

Frank J. Fabin

Subscribed and sworn to before me
this 10th day of December, 2001.

Susan M Dacko

Notary Public

SUSAN M. DACKO
NOTARY PUBLIC MINNESOTA
My Comm. Expires Jan. 31 2005

Patent
Case No: 48317US014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
DANIEL A. JAPUNTICH ET AL.
Serial No.: 08/240,877
Filed: May 11, 1994
For: UNIDIRECTIONAL FLUID VALVE

Group Art Unit: 3761

Examiner: A. Lewis

DECLARATION OF ROBERT BETTS

I, Robert Betts, state as follows:

1. In 1965 I began building and repairing 2 and 4-cycle engines and continue to do so today.

2. I presently work for and own Assault Motor Sports, a unit of General Tool and Engineering Inc. Assault Motor Sports is involved in producing and modifying high-performance 2-stroke engines. In the past year alone, I estimate that I have constructed over 30 2-cycle, high-performance engines, all of which have had reed valves. The total number of 2-cycle engines that I have either built or worked on in my 36+ years probably exceeds 250 engines.

3. I have reviewed U.S. Patent 3,191,618 to C.D. McKim. This patent describes a curve seat reed valve that is useful in a 2-cycle engine. In particular, the patent discloses a valve reed 14, of spring sheet material, such as, for example, shim stock, that is secured by an anchor bar 15 and screw 17 to a curve seat 18 that is formed on the inner or engine side of a valve block 10. The mail thrust of the disclosure in the McKim patent is to the use of the curved valve seat 18, which is configured to conform to the normal curvature of the valve reed 14. To define this curvature, the valve reed 14 is mounted at an end portion 27 as shown in Fig. 3 and is stressed by applying a T-shaped member 30 at the free end 29 of the reed 14. The flexed curvature that is created is reproduced on the valve seat 18.

4. I have also reviewed the disclosure in U.S. Patent application Serial No. 08/240,877. I understand that this application discloses an exhalation valve for a filtering face mask. The exhalation valve uses a flexible flap as the dynamic member for opening and closing the valve. The application defines the term flexible to mean that "the flap can deform or bend in the form of a

EXHIBIT E

self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see e.g., Fig. 5)."

5. Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated this 7th day of December, 2001.

Robert Betts

Witness

Witness

EXHIBIT F

Moldex Mask

EXHIBIT G

Survivair Mask